A PROSPECTIVE, RANDOMIZED STUDY OF TISSUE ADHESIVE VERSUS STANDARD WOUND CLOSURE TECHNIQUE FOR LAPAROSCOPIC ABDOMINAL PROCEDURE

By

DR NOR HUDA MAT ALI

Dissertation Submitted In Partial Fulfilment Of The Requirement For The Degree Of Masters In Medicine

(Obstetrics and Gynaecology)

SCHOOL OF MEDICAL SCIENCES, UNIVERSITI SAINS MALAYSIA

MAY 2007

To

My beloved husband, Mohd Nizam Hassan

A strong determinant person

His loves, patience, understanding and moral support enables me to complete this project and my master programme.

My parents

Mat Ali bin Ismail & Rafiah Muda

Their loves and constant moral support makes me a better and stronger person

My three children

Aisyah, Harith, Hazreen

Their cheers and smiles relief my stresses

ACKNOWLEDGEMENT

Alhamdulillah, with the help of Allah Subhanahuwataala, the author was able to complete this dissertation project according to the schedule. The author would like to express her deepest gratitude and thanks to many people who were direct or indirectly contributed to the preparation and completion of this project and manuscript:

- My supervisor, Associate Professor Dr Nik Hazlina Nik Hussain, Lecturer of Obstetrics and Gynaecology Department, Hospital Universiti Sains Malaysia. Her enthusiasm on research had inspires the author and give courage to complete the project. Thank you very much for her guidance, patience and great knowledge on the research field.
- My co-supervisor. Datuk Dr Ghazali Ismail, Head of Obstetrics and Gynaecology Department, Hospital Tengku Ampuan Afzan, Kuantan. Without his contribution, this project might not be possible.
- Dr Norliza bt Mohd Ibrahim, Medical Officer in Hospital Tengku Ampuan Afzan for her full cooperation and kind help during the period of data collection.
- Cik Shamsurnanie bt Mohamed Zukri, a lecturer in Department of Information Technology and Quantitative Sciences, Universiti Teknologi MARA, Pulau Pinang. Her biostatistics expertise enabled this project to be analyzed and submitted.
- All the specialists, medical officers, staffs in Obstetrics and Gynaecology Department and Operation Theatre, Hospital Tengku Ampuan Afzan, Kuantan
- Everyone who has contributed to my training throughout my MMED programme.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

B.C	Before Christ
BTL	Bilateral Tubal Ligation
CI	Confidence Interval
CO2	Carbon Dioxide
DNA	Deoxyribonucleic acid
Gynae	Gynaecology
g	Gram
HTAA	Hospital Tengku Ampuan Afzan
HUSM	Hospital Universiti Sains Malaysia
IQR	Inter Quantile Ratio
l/min	Litre per minute
LUNA	Laparoscopic Uterine Nerve Ablation
LAVH	Laparoscopic Assisted Vaginal Hysterectomy
mg	Milligram
mmHg	Millimetre of Mercury
mm	Millimetre
OT	Operation Theatre
PDS	Polydiaxone Suture
PMR	Penilaian Menengah Rendah
RM	Ringgit Malaysia

SD	Standard Deviation
SPSS	Statistical Software for Social Sciences
SPM	Sijil Pelajaran Malaysia
SRP	Sijil Rendah Pelajaran
VAS	Visual Analogue Score

ABSTRAK (Versi Melayu)

Kajian Prospektif Membandingkan Keberkesanan Gam Pelekat dan Benang Dexon untuk Kes-Kes Pembedahan Laparoskop.

Objektif: Untuk membandingkan keberkesanan antara gam pelekat (Cyanoacrylate) dan benang dexon (dexon 3-0) dari segi masa yang digunakan, kepuasan pesakit serta pemerhatian komplikasi di dalam proses penutupan kulit bagi pesakit yang menjalani pembedahan laparoskop.

Bentuk: Penyelidikan prospektif secara rawak

Tempat: Wad ginekologi, Hospital Tengku Ampuan Afzan, Kuantan dari April 2005 hingga November 2006.

Penglibatan: Seramai 64 pesakit yang menjalani pembedahan laparoskop.

Metodologi: Pesakit-pesakit yang memenuhi syarat tertentu secara inklusi atau ekslusi yang telah dipilih secara rawak samada menerima gam pelekat atau benang dexon.

Ukuran Penilaian: Catitan dan pemerhatian yang dijalankan ialah komplikasi terbabit (darah beku, jangkitan, jahitan terbuka semula), kepuasan pesakit dan masa yang digunakan.

Keputusan:

64 pesakit telah dimasukkan kedalam kajian ini dimana seramai 32 orang untuk kumpulan benang dexon manakala 32 lagi untuk kumpulan gam pelekat. Tidak ada perbezaan ketara antara kedua-dua kumpulan dari segi umur, bilangan anak,tahap pelajaran, pekerjaan dan juga bilangan lubang untuk pembedahan ini. Di dalam kajian ini terdapat perbezaan yang ketara dari segi masa yang digunakan untuk penutupan kulit (benang dexon:7.0±4.2, gam pelekat:4.3±1.0, p=0.002). Dari segi kesakitan pada hari pertama pembedahan, tidak terdapat perbezaan ketara (benang dexon:3.8±2.0, gam pelekat :4.3±1.7 ,p=0.344). Tidak terdapat pesakit yang mengalami pembekuan darah pada hari ke-7 ataupun hari ke-21. Juga tidak terdapat perbezaan ketara dari segi jangkitan kuman atau luka terbuka. Kepuasan pesakit adalah setaraf bagi kedua-dua kumpulan (benang dexon:8.4±1.5, gam pelekat:8.0±1.8 p=0.26). Terdapat perbezaan ketara bagi percantuman kulit pada hari ke-7 (benang dexon:8.1±0.7, gam pelekat:7.3±1.2, p=0.001). Namun begitu tiada perbezaan dari segi percantuman kulit pada hari ke-21.

Kesimpulan:

Di dalam kajian ini didapati perbezaan yang ketara dari segi masa, di mana gam pelekat mengambil masa yang lebih cepat dan singkat bagi proses penutupan kulit bagi pesakit yang menjalani pembedahan laparoskop. Walhal dari segi kepuasan pesakit dan pemerhatian komplikasi ianya adalah setara sama ada dengan menggunakan benang dexon ataupun gam pelekat. Gam pelekat adalah mudah dan selamat untuk digunakan dimana komplikasi yang terbabit adalah setara dengan benang dexon. Ia juga menghasilkan keputusan yang setaraf dari segi kosmetik. Oleh itu ia boleh dijadikan pengganti benang dexon di dalam penutupan luka-luka kecil.

ABSTRACT

A Prospective, Randomized, Study Of Tissue Adhesive Versus Standard Wound Closure Technique For Laparoscopic Abdominal Procedure.

Objective: To compare the effectiveness of cyanoacrylate tissue adhesive with conventional suture in closing laparoscopic abdominal incision.

Design: Prospective, randomized controlled study

Setting: Gynaecology ward of Hospital Tengku Ampuan Afzan, Kuantan from April 2005 till November 2006.

Participants: 64 patients for laparoscopic abdominal procedure

Methodology: Patients were chosen based on inclusion and exclusion criteria . They were then randomly assigned to receive either tissue adhesive or suture.

Main outcome measure: Time taken for skin closure, Post operative day one, Complications such as haematoma formation, wound infection ,wound dehiscence as well as patient's satisfaction.

Result:

Sixty four patients were recruited into the study: 32 in suture group and 32 in tissue adhesive group. Both groups were comparable with respect to age, parity, education level, type of occupation and number of holes.

There was a significant difference in the time taken for skin closure (suture: 7.0±4.2 , tissue adhesive:4.3±1.0, p=0.002). No difference in Day 1 post operative pain (suture:3.8±2.0, tissue adhesive:4.3±1.7,p=0.344). No patients were reported to have any haematoma at either day 7 and day 21. No significant difference in wound infection and wound dehiscence at day 7 and day 21 in each groups. Patients satisfaction was also comparable in either group (suture:8.4±1.5, tissue adhesive:8.0±1.8 p=0.26). There was a significant difference in skin apposition at day 7 (suture:8.1±0.7, tissue adhesive:7.3±1.2 p=0.001). However no difference in skin apposition at day 21.

Conclusion:

In the study, there was a significant difference in time taken for skin closure where tissue adhesive was much more faster compared to suture. Whereas in terms of complications

and patient's satisfaction they were comparable in both two groups. The use of tissue adhesive is easy and safe with complications comparable to suture and results in equally good cosmesis. Therefore tissue adhesive is a suitable alternative to suture in small wounds and low tension areas.

SECTION 1:

INTRODUCTION AND LITERATURE REVIEW

1. LAPAROSCOPIC ABDOMINAL PROCEDURE
2. WOUND HEALING
3. SUTURE MATERIAL
4. TISSUE ADHESIVE

LAPAROSCOPIC ABDOMINAL PROCEDURE

1.1(i) DEFINITION , HISTORICAL

A minimally invasive approach to abdominal surgery where rigid tubes are inserted through small incisions into abdominal cavity. Tubes allow introduction of small camera, surgical instruments and gases into cavity for direct or indirect visualization and treatment of abdomen (Anonymous, 2007)

Laparoscope comes from two greek words. 'Lapara' means the soft parts of body between the ribs margin and hips. 'Scope' comes from greek word 'skopein' means to see or view or examine

1805- ***BOZZANI*** was first to attempt to visualize the interior of a body cavity. He visualized the human urethra in a living subject for the first time using candlelight and cumbersome tube as endoscope.

1826- ***SEGALAS*** refined the technique of urethroscopy by adding a cannula to endoscope tube

1853- ***DESORMEAUX*** developed the first serviceable urethroscope and cystoscope usings mirrors to reflect light of a kerosene lamp.*By the end of 19th century*, cystoscopy and other open endoscopic procedure eg: bronchoscopy, laryngoscopy and oesophagoscopy were well established in daily clinical.

1901-***OTT*** introduced endoscopic inspection of abdominal cavity. He inspected the abdominal cavity with the help of headmirror and a speculum which was introduced through a small abdominal wall incision.

1901- ***KELLING*** demonstrated the use of closed cavity endoscopy for the first time. He first inserted a needle into peritoneal cavity of living dogs and distended it with air. He then inserted a Nitze cystoscope at another site for viewing.

1910- ***JACOBEAUS*** was first to report the use pneumoperitoneum and inspection of abdominal cavity with cystoscope in human beings. Kelling and Jacobeaus are the 'father' of what we know today as laparoscopy.

1920-***ORNIDOFF*** developed a sharp, pyramidal point on the trochar to fascilitate puncture of abdominal cavity after pneumoperitoneum had been created.

1924-***ZOLLIKOFER*** was the first to use carbon dioxide (CO2) as a gas of choice for insufflation because it was easily and quickly absorbed.

1938-***VERESS*** introduced a new type of pneumoperitoneum needle with a spring-loaded blunt probe surrounded by a sharp outer sleeve. This needle provided additional safety in preventing intra abdominal, soft tissue perforations. Initially laparoscopy was used for the diagnosis of pelvic pain and infertility but with the development of specially designed long surgical instrument, it is now possible to perform surgical procedures such as divisions of adhesions, treatment of benign ovarian cysts and female sterilization procedure.

1988-***HARRY REICH*** in Kenningston, Pennsylvania performed the world's first laparoscopic hysterectomy.

1.1(ii) DIAGNOSTIC LAPAROSCOPY

Laparoscopy can be used either for diagnostic or to treat various condition. This allows the doctor to look at structures inside the abdomen whether it is normal or not. Examples includes:

- To diagnose case of abdominal pain, pelvic pain, infertility and other problems in abdominal organ
- Biopsy can be taken during diagnostic laparoscopy
- Staging of certain kinds of cancer can be determined

1.1(iii) SURGERY/THERAPEUTIC LAPAROSCOPY

This type of laparoscopy allows the doctors to treat a disease or condition. It involves removing of disease tissue or repairing damage to a structure in the abdomen. It also can be used in assisted reproductive procedure for women who are infertile.

The development of microsurgical techniques can prevent rough handling of the tissues. Less adhesions are formed following laparoscopic surgery . Electrosurgery also will reduce a degree of tissue ischaemia which is the main initiating factor for adhesion. Apart from

that, recovery is much less painful. Patients can go home sooner. Rapid return to work results in cost benefit to employer (Sutton, 1999)

1.1 (iv) **INDICATION**

TABLE 1: Indications of laparoscopic procedure

1. Excision of endometriosis
2. Division of pelvic adhesions
3. Tubal sterilization- Bilateral tubal ligation
   -Bilateral fimbriectomy
4. Division of bowel adhesions
5. Dye insufflation for tubal patency
6. Ovarian cyst excision
7. Laparoscopic Uterine Nerve Ablation (LUNA) and presacral neurectomy
8. Laser drilling to polycystic ovaries
9. Salphingostomy or Salphingectomy
10. Tubal surgery
11. Oopherectomy
12. Ventrosuspension
13. Pelvic and para-aortic lymphadenectomy and pelvic side wall dissection
14. Myomectomy and myolysis
15. Laparoscopic hysterectomy and vaginal assisted hysterectomy
16. Aquadissection and drainage of tuboovarian abscess
17. Laparoscopic colposuspension and enterocele repair
18. Ureteric repair, ureteronephrostomy

1.1(v) **CONTRAINDICATION**

TABLE 2: CONTRAINDICATION OF LAPAROSCOPY (Sutton, 1999)

ABSOLUTE	RELATIVE
Mechanical and Paralytic ileus	Multiple abdominal incision
Large abdominal mass	Abdominal wall sepsis
Generalized peritonitis	Gross obesity
Irreducible external hernia	Hiatus hernia
Cardiac failure	Ischaemic heart disease
Recent myocardial infarction	Blood dyscrasias and coagulopathy
Cardiac conduction defects	
Respiratory failure	
Severe obstructive airway disease	
Shock	

Mechanical and paralytic ileus can lead to abdominal distension which is an absolute contraindication because of dangers of bowel trauma and perforation.

In severe cardiac and respiratory disease, intraperitoneal gases under pressure can aggravate anaesthetic risks due to effects on acid-base balance, myocardial contractility, venous return and blood pressure (Sutton, 1999) . Severe cardiac disease remains contraindication if the patients cannot tolerate the supine or trendelenburg position.

Acute peritonitis with bowel distension and obstruction is a contraindication since the patient will need the laparotomy to relieve obstruction. However diagnostic laparoscopy is useful in peritonitis of unclear etiology.

As for relative contraindications, it depends on the experience of laparoscopic surgeon and anaesthetist. Previous surgery is associated with greater than 20% risk of adhesions of bowel or omentum to anterior abdominal wall. Therefore adjustment of techniques is needed to minimize risk of bowel injury

Abdominal hernias are not a strong contraindication as was once thought. If appropriate intraabdominal pressure can be maintained, inguinal or umbilical hernias will not be disrupted (Hulka and Reich, 1994).

Patients under anticoagulation therapy for cardiac and thrombotic disease may not be an appropriate candidate. Complete reversal is necessary before this invasive procedure is performed.

1.4 TECHNIQUES

A careful preoperative procedure is essential before performing laparoscope eg: review the indication and contraindication. Informed consent should be taken and explanation regarding the risks, complications and alternatives treatment that are available. The operating equipment must be checked and patient is positioned appropriately. Incision is made within the umbilicus. In closed laparoscopy, the veress needle is inserted and advanced carefully through the layers of abdominal wall towards the cavity. After insertion the needle is connected to carbon dioxide (CO2) insufflator flowing at 1 l/min. Carbon dioxide is generally used as it is quickly absorbed. Therefore the risk of embolism is lesser. The abdomen is then percussed for the characteristic uniform tympanitic sound. Once the liver dullness is lost, gas flow is increased until the pressure of peritoneum reaches between 18-25 mmHg. A short primary trochar is introduced at first vertically guarded by index finger till peritoneum is punctured then it is angled towards anterior pelvis. Then sharp trochar point is withdrawn and gas is released to reduced pressure to 15 mmHg for the duration of operation (Sutton, 1999)

In open technique, a small subumbilical laparotomy incision is made under direct vision and blunt Hasson's trochar is inserted. This method is more popular with general surgery as it should eliminate major vascular injury . All secondary and tertiary trochars must be inserted under direct vision. The inferior epigastric vessels must be identified and can be seen running lateral to obliterated umbilical artery. It must be avoided. The trochar is inserted lateral to this vessels (on avascular area). Most laparoscopic surgical instruments are about 30 cm, and are inserted through one of the port. It requires a good hand and eye coordination. These skills can be achieved through a training and practice on models in an endosurgical training laboratory .